

The Maryland Board of Pharmacy March 18, 1998 Public Meeting Minutes

1. Call to Order and Notice of Conflict of Interest.

President and meeting Chair David Russo called the meeting to order at 8.45 A.M. In attendance were David Russo, President, W. Irving Lottier, Jr., Secretary; Commissioners Stanton Ades, Wayne Dyke, George Voxakis, Dorothy Levi, Barbara Jackson, and Rev. William Johnson; Board Counsel, Paul Ballard; Board staff, David Denoyer, Pam Owens, and Carol Gibbs.

Guests Present include:

Tina Eagan, Dennis Burton Carlos Ortiz and Bob Landsman, CVS Pharmacy
Harold Jones, Division of Drug Control
Robert Vlk, Purdue
Nathan Gruz, Melvin Rubin, Pharmacists
Robert J. Boerner, MPHA
Tim Richardson, Jennifer Duncan, MMA

President Russo requested that any member of the Board with a conflict of interest with an items on the agenda notify the Board at this time. No Board members reported conflicts.

2. Minutes

Mr. Russo requested that Board members review and approve the minutes. Secretary Lottier discussed several corrections. On page 1, "Mr. Hasan Gruz" should be "Nathan Gruz." On page 6, last line says "...students at the school for engaging in medication School has indicated...." It should say "...students at the school for engaging in medication administration. The medical school has indicated." On page seven first full paragraph currently says "develop a parallel course." It should say "course of study." On Page 10, number 4, fifth line, the word "requires" should be "requirements."

Ms. Jackson moved for approval with the suggested amendments, second by Mr. Ades. The motion passed with no opposition.

3. Reciprocity

Mr. Dyke reported sixteen candidates met yesterday, and all completed the requirements with the exception of Stephen Miller, and Wai-Ming Wong who are pending taking the oral English competency test. The following candidates attended:

Michael Beatty, Michele Farrington, Melissa Beatty, Carl Kendrick, Jean Beving,
Ebenezer Oyeboode, Sebele Desta, Gary Smith, Audry Fischer, Brian Spiker, Jae Kap Kim,

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Aloina Walizada, Sursh Babu V. V. Kota, Stephen Miller, Jr., Dennis Olig, and Mai-Ming Wong.

Ms. Jackson moved to accept all with the conditional acceptance of the two candidates awaiting the English test. Mr. Lottier seconded the motion and it was approved.

4. Executive Director's Report

A. Report from CVS

Mr. Russo introduced Tina Eagan, Dennis Burton and Carlos Ortiz. Robert Landsman from CVS presented some background regarding the report in Washington Post of February 15, 1998.

Mr. Ortiz stated that CVS representatives wished to clarify some of the misinformation circulating and presented background on CVS's pharmacy compliance and health education programs. He stated that CVS never sold names to manufacturers, that CVS merely contracted with manufacturers to offset the cost of the mailings. CVS then provided Elensys with patient names and addresses so that Elensys could send the reminders. No patient profiles were released and each employee of the mailing firm signed a non-disclosure contract with CVS. All information was returned to CVS after each mailing. Ms. Tina Eagan stated that every CVS and Elensys employee contract had specific confidentiality provisions. Additionally, the agency relationship between CVS and Elensys was documented. There were strict guidelines providing for computer security and the program was restricted to "non-sensitive" drugs.

Mr. Ortiz explained the reason underlying CVS's desire to send reminders by mail rather than point of service reminders. He stated that the main reason for choosing mail reminders as opposed to point of service reminders was because of manpower issues and the difficulty in obtaining informed consent.

Dennis Burton explained that the goal of the reminder program was to improve patient adherence and assist patients towards better outcomes. The program also sought to inform patients of newly available drugs.

Mr. Burton proved examples letters that were actually mailed to patients. These letters dealt with drugs such as Zyban and Posicor which are used for smoking cessation and hypertension. All letters were reviewed and submitted to the FDA as promotional activity and CVS sent a patient promotional information (PPI) with most. The letter also offered patients an explanation of how to opt out of the reminder program so that they would not receive further letters if they did not want to.

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Mr. Burton also stated that CVS had received numerous complaints since the Post article. Most centered around patient fears that their names and confidential information had been given to other organizations. CVS ran a letter in the Post clarifying that they had not sold names and ultimately canceled the reminder program.

Questions for CVS from the Board and Staff

Commissioner Levi: Q: What other information was disclosed? A: Name and address, date of refill .

Pam Owens: Q: How did the opt out program work? Did a patient have to opt out of each mailing, each drug, each drug class, or only once? A: If a patient opts out, their name is deleted from the list and they are never again sent mailings on any matter.

Stanton Ades: Q: Mr. Ades stated that the program appeared to present a potential opportunity and asked if and how the customers were informed beforehand. A: They were not informed. CVS considered making it an opt in program by asking for informed consent at point of purchase but determined that it would be too difficult to obtain true informed consent given the time constraints on pharmacists.

Mr. Ballard: Q: Are refill reminders sent only to patients who use drugs that are funded by manufacturers? A: Refill reminders are not sent on all drugs.

Ms. Jackson: Q: How many mailings were sent? A: 12 thousand mailings in Maryland.

Mr. Russo summarized by stating the Board has been asked to approve several similar programs. He cited the examples of Elensys and McKesson. The Board recognized the value of such compliance programs, but the Board is concerned with out-sourcing the mailings. The Board also believes that customers expect that the data that they provide to a pharmacy will not be redisclosed to an outside company, no matter how innocent the disclosure. The Board has consistently recommended that consent be obtained prospectively and that the pharmacy or pharmacy corporation assume the responsibility for mailings.

Mr. Burton noted that there is a Federal proposal in the works, in fact the Senate Labor Committee has set a deadline as of August 1999 for the Secretary of HHS to adopt regulations. Senator Jefford's Office has shown interest in a bill which would require patient release every time any information is communicated. Mr Ortiz stated that the Federal proposal may be a problem for pharmacists who must often release patient information to agents.

B. Senate and House Budget Hearings - Tamarra Banks

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Ms. Banks reported that both chambers are currently reviewing the 1999 budget. The Senate is recommending that \$13,000 be cut from the 1999 appropriation. Most boards received a cut primarily in per diems and travel. Ms. Banks reported that the Board will be able to find savings in another category and that the cut is modest and will cause no operating problems for the Board.

C. Toxsense - Board Media Campaign - George Voxakis/Tamarra Banks

Ms. Banks stated that the media campaign was underway. Mr. Robinson and Ms. Duncan, from MMA, gave a brief presentation.

Mr. Robinson gave a brief overview, stating first that they were awarded opportunity to work with this campaign in the fall. They developed the logo "Avoid toxins use toxsense." This logo will accompany all promotional items. They presented posters and other promotional items that will be used in the campaign. Some promotional materials dealt with pharmacies and pharmacists while the others dealt with the Poison Center. The promotional materials relating to pharmacy will contain tag lines such as: "Pharmacies and Pharmacists - Dispensing help in your community" "Years of study, discipline and testing go into every bottle"; and, "For maximum results mix our advice with your medication." The promotional materials relating to the Poison Center will contain tag lines such as: "The Poison Center - We never close"; "Over 50,000 served annually - your child could be next"; "Over one million substances can kill, one call can save"; and "One call save can save, 365 days a year, twenty four hours a day."

The first phase will target parents of pre-school children. The first step is to educate children and their parents about poisonings and adverse drug actions. The plan is to emphasize to the community to call a pharmacist for questions regarding drug interactions, and the poison center for drug or poisoning emergencies.

Another goal of the campaign is to educate the public regarding the staff of the Poison Control Center. MMA seeks to dispel the myth that the center is operated by untrained volunteers and to instill the understanding that it is staffed by professionals and is the first place to call in the event of a poisoning.

Ms. Duncan reported that information was sent to 95 print publications and the posters will be delivered to pharmacies in Maryland. This particular program will last approximately six months

MMA is also looking into running bus and billboard adds and into producing a public service announcement (PSA). They have also begun to enlist corporate sponsorship from companies like Rite Aid, Giant, Home Depot and Hechingers. MMA is also developing contacts with the Maryland Department of Education, and the Parks and Recreation Department.

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Board members commented that they saw posters at midyear and that they were helpful at MPhA. Board members noted that it would be nice to get some of the posters in the schools. Ms. Jackson noted that the Maryland Teacher's Association could participate.

5. Board Counsel's Report

HB 267 Follow-up

Mr. Russo stated due to the status of this bill this issue may be moot, but that Mr. Ballard should present his findings because the bill may be attempted again next year.

Mr. Ballard stated that the professional activity permitted by the medication administration legislation may be a technical violation of the Federal Food, Drug and Cosmetic Act because specific patient names would not be required on "prescription" for immunizations. However, after consideration, Mr. Ballard believes that this specific Federal provision has not been strictly enforced. Nurses, for example, are currently administering medications without the benefit of an individual name on each prescription to administer an immunization. Pharmacists are proposing to follow the same protocol as nurses when engaging in administering immunizations. However, Mr. Ballard suggested that for next iteration of the legislative proposal that "administration" be limited to giving vaccines.

6. Task Force/Strategic Planning Reports

A. Status Report on HB 267 and HB 1187

David Russo and Pam Owens stated that HB 267 did not make it out of Committee. The Committee vote was on Friday, the 13th of March. The exact Committee vote was not known..

Ms. Owens reported that the Committee vote on HB 1187 was favorable at 18 to 3. Some amendments were offered in Committee. The first amendment was the inclusion a peer review committee to review agreements. The peer review committee will be composed of one Board member, two representative appointed by the Board and two representatives appointed by the appropriate prescriber Board. Another provision was amended onto the bill stating that no prescriber may be coerced into entering into an agreement. The final amendment prohibits entering into an agreement to collaborate in therapy involving any audiological device. The full House vote will be on Thursday (March 26).

Ms. Owens has provided Mr. Pica and Mr Alexander (Lobbyists) with a one page list of bullet points to help with the lobbying efforts. Ms. Owens has also contacted various pharmacy groups

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to ask that respective members contact their individual Legislator. Del. Owings has not yet informed the Board whether he will restrict testimony to “sponsor only” if the Bill crosses over to the Senate.

7. Committee Reports

A. Licensing Committee - Wayne Dyke

(I) Examination Schedule

Mr. Dyke is working with the school to schedule the examination. We may be able to conduct the examination in one day.

(ii) Committee Schedule

Mr. Dyke reported that the Committee will schedule a meeting for April.

B. Legislative Committee

1. Legislative Positions

A. SB 412 and HB 1062 Consumer Protection - Drug Storage Shipment Safety

Ms. Owens stated that this bill was initiated by Epic and will apply to all pharmacies who deliver drugs to patients unless they are hand-delivered directly to a patient or the patient’s agent. The purpose of the law was to react to USP’s study of temperatures in drug delivery. It had a hearing in the Senate Committee on 2/27/98 and a hearing in the House Committee March 5th. As of this time there are no Committee reports. The Board offered amendments which corrected technical problems with the bill involving placement of the new material. The substance of the final amendments are being contested by AARP Pharmacy Services. EPIC is working with AARP to find common ground. The substantive amendments will likely do away with the requirement that mail order pharmacies keep a separate dedicated phone line to answer questions regarding chemical degradation of drugs. The Board would support with such an amendment and supports the Bill.

Mr. Ades commented that an unintended consequence may be increased

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costs for pharmacies.

- B. HB 765 Task Force on Pharmacy Technicians - Defeated by the Environmental Matters Committee

This Bill received an unfavorable report due in part to concern about legislative staffing in an election year. The Board is examining the issue of Pharmacy technicians in the Pharmacy Practice Committee and will report to Delegate Goldwater.

- C. HB 444 and SB 363 Licensed Physical Therapist and Licensed Physical Therapist Assistants - Topical Pharmaceutical Agents

Both bills have been heard in their respective Committees, however, no reports have been issued.

- D. HB 139 Unspent Funds - Waiting List Equity Fund

The Board opposed this Bill as did all other health occupations Boards. Dr. Voxakis testified against the bill and it received an unfavorable report from the Committee.

- E. HB 803 and SB 352 Health Occupations - Boards - Project Reserve Funds

This bill would allow the Boards to create a new budget line item for litigation or legislative mandates. The HB came out of committee and had a floor vote on 3/10/98. The bill has been special ordered two times by Del. Levay. The special order may have to do with a drafting problem that is being corrected by amendment. The Bill is due for a full House vote again on March 19.

- F. HB 383 - Disclosure of Information - Insurance Fraud Division

HB 383 had a Committee hearing on 2/24/98. There is no Committee report at this time.

- G. HB 1019 - Nurse Psychotherapists - Authority to Prescribe Medications

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This Bill had a hearing on March 3rd. No report from committee as of yet. BPQA has informed Ms. Owens that it looks good for this bill.

H. HB 1094 - Physician Assistants - Physicians Delegated prescriptive Authority

The Committee hearing for this bill was 3/5/98. There has been no report from committee on this bill at this time.

I. New item. SB 782 - Advisory Committee on Home Based Health Care Services

This bill was initiated by L&C's Carol Benner. It creates an advisory committee to study all laws, regulations, and policies pertaining to home-based care. It requires that the committee report findings and suggestions to the Secretary by a given date. It effects the Board only in that it provides for one of the committee members to be a representative from the Board of Pharmacy. The Board took no position on the bill.

J. New item. HB 1408 - Heath Carriers - Drug Substitution - Notification (Delegate Bozman)

Ms. Owens informed the Board that this bill would require health insurers to inform patients when they required a pharmacist to switch a drug.

The Board agreed provisionally to support the bill and to vest the authority in Dr. Voxakis, Mr. Russo and Ms. Jackson to make a final support decision after Ms. Owens gets more information on how this bill will be operationalized..

Motion by Dr. Voxakis, seconded by Ms. Jackson to support this bill and delegate the authority to take appropriate action. This motion passed with no objections.

2. Regulation Update

a. Follow-up on Pending Regulations

(I) 10.34.15 Notice

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This regulation is final awaiting signature of the Secretary.
(ii) 10.34.20 - See Pharmacy Practice item

C. PEAC Update - Stanton Ades

Mr. Ades attended the last PEAC meeting. The Committee discussed presentation at the midyear conference, which was well received. The information helped to spread knowledge about PEAC and to increase awareness of the program. In addition, the PEAC sponsored "Mocktail" party went well.

Mr. Ades also informed the Board that the move to develop 501(c)(3) nonprofit status is almost completed.

Mr. Denoyer reported briefly on a March Conference focusing on the issue of chemically dependent health care professionals. He will have a written report for next month.

D. Pharmacy Practice Committee - Stanton Ades

1. Code of Conduct

The Code of Conduct has been drafted and approved by the Practice Committee. Mr. Ades asked the Board members to review it for next months meeting and be prepared to vote on its adoption.

2. Assisted Living

The Practice committee last met on March 11. The proposed assisted living regulations were discussed. The Committee drafted a letter to Ms. Benner in L&C. The letter addresses several concerns about assisted living medication management. Mr. Ades suggested the Board send the letter included in the hand-out.

Ms. Levi commented about the involvement of pharmacists in the training of personnel. She noted that thirty percent of the patients in a small survey group self-administer and the medications are kept at bedside in a locked box. She noted that the physicians do write orders for self medication on admission. The Board could make a change to the letter which allows for documentation of fitness to self-administer on the patient's admission sheet.

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Mr. Ades motioned to accept the letter if last sentence of the second to last paragraph is deleted. Also, the second sentence of the second paragraph should be highlighted. Mr. Ades moved to send the letter as amended and the motion passed with none opposed.

3. Electronic Transmission of Prescriptions.

This proposed regulation is also included in the packet. Mr. Ades again asked the Board to review it and be prepared to vote on it in the Board's April meeting.

4. Proposal to adopt new regulations for Assisted Living Program See above.

E. Budget Committee

1. Policies for Monitoring of Budget Items Reviewed by the Legislative Auditor

Ms. Banks informed the Board that she is having difficulty documenting specific expenditures relating to Board member activity and expenditures for per diems to ensure that per diems expenses do not significantly exceed the appropriation. In order to better document expenditures related to per diems that could be used when Legislative Auditors raise questions about them, she suggested creating a sign in sheet for committee and task force meetings held by the Board. The sign in sheets would include information on who attended and the attendees time of arrival and departure. A comment section would allow Board members to indicate when they worked on other Board business while attending a committee meeting or case resolution conference. A motion was made by Irving Lottier and seconded by Barbara Jackson to initiate a procedure for documenting expenditures related to per diems effective April 1, 1998. Staff will present an easy method for completing such documentation to the Board at the April meeting.

2. Follow-up Questions Regarding Second Quarter Projections

Ms. Banks presented the Second Quarter report. She noted that we are on target. Board members did not ask questions about the report.

F. End of Life Task Force - Stanton Ades

Mr. Ades informed the Board that the Committee is still together but has not

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recently met.

8. Questions for the Board

A. Past Inquiry

1. CLIA Regulations (Testing Equipment Use) - Pamela Owens

Ms Owens reported that if the legislation involving collaborative practice passes, there will be other regulations, such as laboratory regulations, which may apply to collaborative practice. She reported that CLIA regulations are federal and that most of the community testing allowed in the collaborative practice bill is CLIA exempt (everything but anticoagulation). However, Maryland also has laboratory regulations that are similar to CLIA and the tests allowed by the collaborative practice bill are not waived under Maryland regulations.

Ms. Owens has met with Michael Wajda of L&C and has thus far determined that the collaborative practice bill generally comports with the Maryland laboratory requirements. That is, the laboratory regulations require a physician to “oversee” the laboratory. Ms. Owens and Mr. Wajda believe that this can be accomplished through the contract that the collaborative practice legislation requires between the pharmacist and the prescriber because the Maryland laboratory regulations do not require that the physician actually be on sight. However, there are other technical requirements that Ms. Owens must research before she can be certain that the testing allowed by the collaborative practice legislation would also be allowed by the laboratory regulations. Mr. Wajda has agreed to work with Ms. Owens and the Board to broaden patient access to certain testing so long as standards are still protected.

B. New Inquiries

1. Telepharmacy Practice Licensure/Registration Survey- NABP

Mr. Denoyer presented a survey from NABP regarding the licensing of “telepharmacy. The Board reviewed the survey and authorized Mr. Denoyer to complete and return it to NABP. Generally, Board members expressed no desire to regulate pharmacists providing advice to Maryland patients, provided the pharmacist are duly licensed in the jurisdiction where the call originated.

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9. Informational

1. Report from the Washington Post - When Private Means Private

Board members did not discuss this item.

2. Long Term Care Pharmacy

Mr. Denoyer stated that he and a representative from Drug Control had visited several long-term care pharmacies to review their procedures for handling drugs. He also stated that some of the pharmacists are willing to come to visit the Board to discuss their procedures. Mr. Denoyer will work with Mr. Ades in developing a meeting with long term care pharmacists.

10. Follow-Up Letters

Board members reviewed, but did not discuss these items.

- A. Pharmacy Automation Systems-Cardinal Health
- B. Support of HB 267-Administration of Drugs
- C. Support of HB 1187-Collaborative Drug Therapy Management
- D. Confidentiality of Pharmacy Records

Respectfully Submitted,

W. Irving Lottier, Jr., Secretary